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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,569

07/11/2003

Robin A. Robinson

NOVV-003/00US

5752

58249

7590

10/31/2006

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/617,569

Applicant(s)

ROBINSON ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

This action is in response to the paper filed 8/10/06.

Claims 34-55 are under consideration.

***Claim Objections Withdrawn***

Claim 44 contains the trademark/trade name Novasomes®.

Applicant has amended the claims and the objection is withdrawn.

***Rejections Withdrawn***

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 52 and 53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims and the rejection is withdrawn.

Claim 48 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claim to recite approximately 80nm and the rejection is withdrawn.

***Rejections Maintained***

***Claim Rejections - 35 USC § 103***

Claims 34-42, and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* (J of Virology Vol 75, pages 6154-6165, from IDS) and Saito *et al.* (Vaccine 2001 Vol. 20 pages 125-133).

Applicant argues that the examiner has not met the burden of proving a prima facie case of obviousness, that the VLPs are made in cells not *in vitro*, points to MPEP 2112 and case law.

Applicant's arguments have been fully considered and not found persuasive.

Latham *et al.* and the specification make the VLPs by insect cells and would be expected to have the same properties. The VLPs of Latham *et al.* react with monoclonal antibodies in western blots and on fixed cells and are stated by Latham *et al.* to be useful as vaccines. The VLPs are shown to look like influenza virus particles (Figure 5). The proteins that make the VLP of Latham *et al.* appear to be wild type in structure and antibody binding. The VLPs of Latham *et al.* would be expected to have the HA and NA

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activity of influenza. The claims recite no structures that differentiate them from the VLPs of Latham *et al.*

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

The rejection is maintained.

#### ***New Rejection***

Claims 34, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* and Saito *et al.* as discussed above and Gupta *et al.* (Vaccine 2001 Vol. 14 pages 219-225).

Applicant argues that Latham *et al.* does not teach avian influenza.

Latham *et al.* and Saito *et al.* are discussed above and the combination result in avian influenza VLPs.

Latham *et al.* and Saito *et al.* do not teach adjuvants.

Gupta *et al.* teach Novasomes are good adjuvants for protein immunogens and induce antibodies as well as reference adjuvants and also stimulate a TH1 like response which is involved in cell mediated immunity (Discussion pages 223-224).

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One of ordinary skill in the art at the time of invention would have been motivated to use adjuvants with the VLPs because they are not living and adjuvants are known to increase the immune response to protein antigens. Latham *et al.* teach that the VLPs can be used as vaccines. One of ordinary skill in the art would be motivated to make vaccine to influenza strains because there is a well known need to protect the people from influenza.

Thus, it would be *prima facie* obvious to make the VLPs of Latham *et al.* and Saito *et al.* with the adjuvants of Gupta *et al.* to make the claimed composition with the expectation of success knowing that adjuvants increase the immune response to protein antigens.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill  
Patent Examiner  
10/24/2006



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